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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/165,546	10/02/98	ALEXANDER	K LUD5466.4-JE

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HM12/1016

EXAMINER

DECLoux, A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 10/16/01

21

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**



### DETAILED ACTION

Note: The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Amy DeCloux, Group Art Unit 1644, Group 1640, Technology Center 1600.

1. Applicant's amendment, faxed 8-6-2001 (Paper No. 20) is acknowledged and has been entered. Claims 6-8, 11-13, 16-54 and 61-84 are pending. Claims 6-8, 11-13, 16-54, and 61-73 are withdrawn from consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.
2. The rejections of record can be found in the previous Office Action, mailed 5-22-01 (Paper No. 19). In view of applicant's amendment, faxed 8-6-2001, the outstanding rejections have been withdrawn. However, in view of Applicant's amended claims, new grounds of rejection have been applied to the instant claims.
3. In Applicant's amendment, faxed 8-6-2001, applicants invite the examiner to "...reconsider the change in position on the restriction and to augment the inadequate explanation for same.". Though the instant examiner wrote neither of said restriction requirements, the instant examiner agrees with Examiner Dibrino that the most recent restriction requirement is indeed proper as outlined in Examiner Dibrino's restriction requirement mailed 1-4-01, and also points out that during the interval between the two restrictions, the sequence searching facilities had become overextended.
4. The oath or declaration stands defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.  
In Applicant's amendment, faxed 8-6-2001, Applicant states that this will be dealt with in the future.
5. In Applicant's amendment, faxed 8-6-2001, applicant states that Point 6 of the previous office action, mailed 5-22-01 (Paper No. 19), is not understood. However, it just means there were duplicate references in the IDS filed 7/2/99 and that filed 4/19/99.

### NEW GROUNDS OF REJECTION

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6-27-00

7. Claims 82 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 82 is not supported by the specification or by the claims as originally filed. There is no support in the specification or claims as originally filed for the recitation of one other polypeptide, the amino acid sequence of which is found in the protein encoded by SEQ ID NO:1, which complexes with an MHC-Class II molecule, said polypeptide "having at least one HLA-DR53 binding motif". There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes **new matter**. Applicant is invited to point out support for the instant phrase with respect to SEQ ID NO:1. *st in C1-1*

8. Newly added claims 74-75, 78 and 82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *28*

The specification does not provide adequate written description of the claimed invention. In the instant case, the specification does not convey to the artisan that the applicant had possession at the time the invention was made, of an isolated polypeptide which 1) binds to MHC Class II HLA-DR53 molecules which comprises at least 18 and no more than 25 amino acids, as recited in claims 74-75 and 78, nor 2) an isolated polypeptide or composition thereof wherein said polypeptide has at least one HLA-DR53 binding motif, said motif consisting of four amino acids as recited in claims 74-75, 78 and 82.

The instant specification does not describe peptides longer than 18 amino acids that bind to MHC Class II HLA-DR53 molecules. Nor does the instant specification describe peptides or a composition thereof, with an HLA-DR53 binding motif consisting of four amino acids; it appears only 2 amino acids of said motif are described. Nor does the instant specification disclose the structure of the subsequences of SEQ ID NO:1 which can be the "at least one other peptide" of the composition recited in claim 82, wherein said other peptide complexes with an MHC-Class II molecule and has at least one HLA-DR53 binding motif, said motif consisting of four amino acids, because only 2 amino acids of said motif are described of said other peptide of undefined length.

The instant specification discloses six polypeptides with the required motif amino acid residues (SEQ ID NO:s 8-13) which bind HLA-DR53, and also discloses that at least three of these polypeptides (SEQ ID NO:s 8-10) sensitize CD4+ T cells to release interferon gamma (see page 29, lines 25-26 and page 30, lines 1014). All of these peptides are 18mers. However, a generic statement such as an isolated polypeptide or composition thereof, that "binds to MHC-Class II HLA DR53 molecules", "comprises at

least 18 and no more than 25 amino acids" and "which has at least one HLA-DR53 binding motif" as recited in claims 74-75 and 78, or a composition comprising "at least one other peptide" the amino acid sequence of which is found in a protein of defined sequence which complexes with an MHC Class II molecule as recited in Claim 82, without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by the recited properties. However the recited properties do not structurally define common features possessed by members of the genus that distinguishes them from others, other than the two amino acid motif. Since the disclosure fails to provide sufficient relevant identifying characteristics that identify members of the genus, and given the broad genus claimed, the disclosure of a few peptides of defined sequence is insufficient to describe the claimed genus.

Applicant contends that since Claim 74 combines now canceled claims 1 and 2, and since claim 2 (which was dependent on claim 1) was not subjected to a 112 first paragraph written description rejection, claim 74 should also not be subjected to a 112 first paragraph written description rejection. However, the written description was directed to phrases recited in claim 1, which are still present in claim 74, and therefore a 112 first paragraph written description rejection has been applied to claim 74 as well as dependent claim 78. Applicant points out that claim 78 corresponds to now canceled claim 9 which was subjected to a 112 first written description rejection in the previous office action. The examiner agrees with applicant's contention that claims 76-77 and claims 79 and 84 should be free of a 112 first paragraph written description rejection. Applicant asserts that now canceled claim 59 has been replaced by claim 82 (from which the examiner infers that applicant contends that said claim should not be subjected to a 112 first written description rejection). However, the examiner notes that claim 82 has an additional limitation when compared to now canceled claim 59, said limitation being said polypeptide having at least one HLA-DR53 binding motif, and therefore a 112 first written description rejection has been applied to claim 82.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

10. Claims 82-83 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claims 82-83 are indefinite in the recitation of "said polypeptide" in line 4 of Claim 82 because it is not clear whether "said polypeptide" refers to the polypeptide first recited on line 1 of claim 82, or if "said polypeptide" refers to the "at least one other polypeptide" recited on line 2 of claim 82. Applicant is requested to clarify. For examination purposes, the latter interpretation is being used.

11. Claim 84 is allowable because the prior art neither teaches nor suggests a composition comprising a first polypeptide consisting of amino acid sequence of SEQ ID NO:7, and at least one other polypeptide, the amino acid sequence of which is set forth at SEQ ID NO4, 5 or 6.

12. Claims 76-77 and 79-81 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. Or a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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October 15, 2001

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ART UNIT 182/1644